MT06 (6 months)

Urinary and sexual function after treatment with temporary implantable nitinol device (iTind) in men with LUTS: 6-month interim results of the MT06 study.

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https://pubmed.ncbi.nlm.nih.gov/32851439/

Introduction and Objective

To evaluate functional and sexual outcomes after treatment with temporary implantable nitinol device (iTind; Medi-Tate Ltd, Israel); a novel minimally-invasive treatment for Lower Urinary Tract Symptoms (LUTS) due to Benign Prostatic Hyperplasia (BPH).

Methods

To report 6 month interim results of a single-arm, multicenter prospective study evaluating functional outcomes after treatment with a temporarily implantable nitinol device (iTind; Medi-Tate Ltd, Israel).

Inclusion Criteria:

- IPSS ≥ 10
- Qmax < 12 mL/s
- Prostate volume < 120 mL

Exclusion Criteria:

- Previous prostate surgery
- Prostate cancer
- Urethral stricture
- Bladder stones
- Urinary tract infection (UTI)
- Obstructing median lobe (considered >1.2 cm)
- Neurological conditions that may affect voiding function

The iTind was implanted within the bladder neck and prostatic urethra using a 22 Fr rigid cystoscope under intravenous sedation and removed 5-7 days later through a 22 Fr Foley catheter under local anesthesia. Patients were not washed-out of BPH medications or required to cease anti-coagulation or anti-platelet therapy prior to the procedure. Postoperative VAS and complications (Clavien Dindo-Grading System) were recorded. Preservation of urinary continence and sexual and ejaculatory function were assessed according to ISI, MSHQ-EjD and SHIM. Post-operative IPSS, QoL, Qmax and PVR were also assessed at 1, 3, and 6 months post-operatively.

Results

This interim report includes results out to 6 months on the first 70 patients enrolled in the study. The median age was 62.31yrs, with an average prostate volume of 37.68mL (15-80mL). Baseline and follow-up data are reported. No intraoperative complications were observed and the average post-operative VAS score was 3.24 ±2.56. On average, patients returned to daily life 4.3 days following the retrieval procedure, and mean quality of recovery visual analog scale (QoR VAS) was 0.77. Significant improvement ($p<0.0001$) from baseline was recorded in IPSS, QoL and Qmax in response to iTind treatment at 6 months. Sexual function and urinary continence were preserved in all subjects according to ISI, SHIM and MSHQ-EjD questionnaires.

Results

	Baseline	6 Month FU (*p* value)
IPSS	21.2	8.3 ($p<0.01$)
QoL	4.1	2.0 ($p<0.01$)
Qmax	7.3 mL/sec	12.0 mL/sec ($p<0.01$)
PVR	69.3 mL	48.1 mL ($p=0.12$)
SHIM	16.1	18.2 ($p=0.06$)
ISI	1.1	0.8 ($p=0.14$)
MSHQ-EjD	9.2	11.2 ($p<0.01$)

Conclusion

iTind is a well-tolerated minimally-invasive treatment for BPH-related LUTS. Interim results demonstrate iTind offers a rapid recovery and return to daily life, preservation of sexual function and urinary continence as well as a significant improvement in symptoms and urinary flow at 6 months follow-up.

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